

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT  
(PCT Article 36 and Rule 70)

REC'D 09 JUN 2004

WIPO PCT

Applicant's or agent's file reference 91.M0105WO7	<b>FOR FURTHER ACTION</b>	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/T 02/00681	International filing date (day/month/year) 28.10.2002	Priority date (day/month/year) 28.05.2002
International Patent Classification (IPC) or both national classification and IPC A61M11/06, A61M11/06		
Applicant MEDEL S.P.A. et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 4 sheets, including this cover sheet.

This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of 2 sheets.

3. This report contains indications relating to the following items:

- I  Basis of the opinion
- II  Priority
- III  Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV  Lack of unity of invention
- V  Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI  Certain documents cited
- VII  Certain defects in the international application
- VIII  Certain observations on the international application

Date of submission of the demand 05.12.2003	Date of completion of this report 08.06.2004
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized Officer  Valfort, C  Telephone No. +49 89 2399-2352



**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/IT 02/00681

**I. Basis of the report**

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

**Description, Pages**

1-8 as originally filed

**Claims, Numbers**

1-4 received on 13.05.2004 with letter of 11.05.2004

**Drawings, Sheets**

1/1 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- the language of publication of the international application (under Rule 48.3(b)).
- the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- contained in the international application in written form.
- filed together with the international application in computer readable form.
- furnished subsequently to this Authority in written form.
- furnished subsequently to this Authority in computer readable form.
- The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- the description, pages:
- the claims, Nos.:
- the drawings, sheets:

**INTERNATIONAL PRELIMINARY  
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5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

*(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)*

6. Additional observations, if necessary:

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes: Claims	1-4
	No: Claims	
Inventive step (IS)	Yes: Claims	1-4
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-4
	No: Claims	

**2. Citations and explanations**

**see separate sheet**

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IT 02/00681

Reference is made to the following documents:

- D1: US-A-5584285
- D2: DE-C-759110
- D3: EP-A-0626180

**Point V**

- 1.1 D1 shows an apparatus for nebulising a liquid, e.g. for aerosol therapy (fig.4) having standard flap valves (140, fig.4). The subject-matter of claim 1 differs from the device of D1 in that a valve having a shutter movable between an open and a blocking position, said shutter being connected to a ring by deformable connecting elements between the ring and the shutter in order to anchor it to a tubular portion of the nebuliser. Moreover, the deformable connecting elements in claim 1 are spiral shaped and have a first end fastened peripherally to the shutter and a second end fastened to the ring. According to claim 1 the valve can be either an exhalation or inhalation valve.
- 1.2 Said construction is supposed to provide a valve with good sealing properties at rest and which oppose minimum resistance to opening/closing (see description page 4 1st paragraph). The problem to be solved by the invention can therefore be regarded as how to improve the valves of the apparatus of D1 to improve sealing and minimize closing/opening pressures of the valve.
- 1.3 A valve similar to the characterising portion of claim 1 is described in document D2, also a check valve for a respiratory appliance (see col.2 lines 1-2 "Atemventil"), (see figures, deformable connecting elements 3, ring 2 tubular portion 1 and shutter 5) as providing the same advantages as in the present application (see col.2 lines 54-63 and lines 69-81). Nevertheless the valve of D2 has straight connecting elements and not spiral shaped elements. Thus a skilled person combining the valve of D2 with the apparatus described in document D1 in order to solve the problem posed, would not arrive at the subject-matter of claim 1. Therefore, the subject-matter of claim 1 appears to fulfill the requirements of Article 33(2) and (3) PCT, concerning novelty and inventive step.
2. Claims 2-4 are dependent on claim 1 and as such also meet the requirements of the PCT with respect to novelty and inventive step.

## CLAIMS

1. Apparatus (1) for nebulising a liquid, in particular for aerosol therapy, of the type comprising:

a nebulising ampoule (2) provided with at least an opening (4;5) for aspirating and/or expelling air from/to the environment and with a mouthpiece (3) for dispensing a nebulisation of medical product;

5 a valve (6) for regulating a flow of air into and/or out of the ampoule (2), said valve (6) being positioned in correspondence with said opening (4;5)  
~~and characterised in that the valve (6) is of the type comprising/~~

10 a shutter (8) able to move between an operative blocking configuration corresponding to an obstruction of said opening (4;5) and an operative configuration of consent to the passage of the flow of air

a ring (9) connected to the shutter (8) to anchor it to a tubular portion (2a) of the ampoule (2), said tubular portion (2a) being positioned in correspondence  
15 and with the opening (4;5)

15 a plurality of deformable connecting elements (10) between the ring (9) and the shutter (8) to allow said shutter (8) to move from said operative blocking configuration to said operative configuration of consent and vice versa, said movement being directly caused by an inspiration and/or expiration phase by a user,

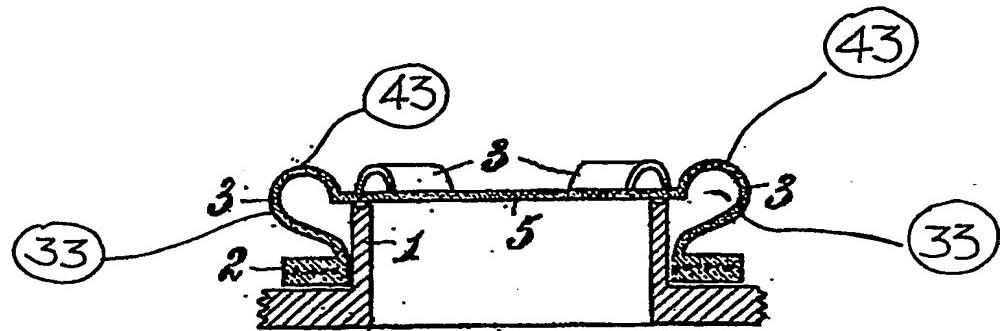
20 2. ~~Apparatus as claimed in claim 1~~, characterised in that the deformable elements (10) are spiral shaped and have a first end fastened peripherally to the shutter (8) and a second end fastened to the ring (9).

2. 3. Apparatus as claimed in claim 1, characterised in that it comprises a holed protective element (11) positioned in correspondence with the opening

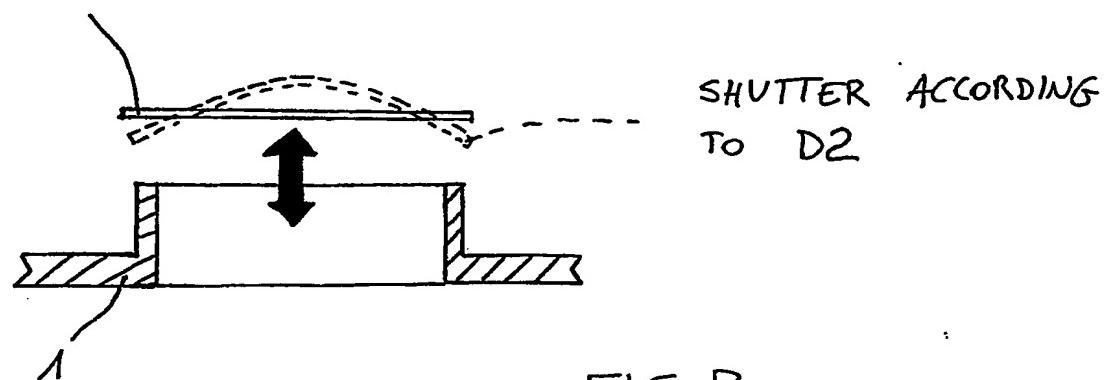
(4;5) to prevent the introduction of foreign bodies into the ampoule (2), preventing any damage to the valve (6).

3. ~~4.~~ Apparatus as claimed in claim 1, characterised in that it comprises a second shutter (12) to cover an opening (5) of the ampoule (2) necessary to expel to the environment air exhaled by a user, said second shutter (12) being a deformable reed-like body having an end (12a) fastened in correspondence with the opening (5) and an end (12b) that is free to move away from the opening (5) to uncover it at least partially and allow the escape of air.

4. ~~5.~~ Apparatus as claimed in claim 1, characterised in that the valve (6) is associated with a so-called supplementary, or secondary, channel (7) of the nebuliser ampoule (2).

FIG. A

SHUTTER ACCORDING  
TO THE PRESENT APPLICATION

FIG. B